

Date

Dear Dr *Name*,

Re: Participant name:

Date of Birth:

Hospital Number:

Address:

RE: multi-Arm Therapeutic study in pre-ICU patients admitted with Covid-19 – Experimental drugs and mechanisms (TACTIC-E)

Your patient was randomised to: EDP 1815

I am writing to inform you that your patient has agreed to participate in the above clinical trial at **local hospital name**.

TACTIC-E is a multicentre, randomised, parallel arm, open-label platform trial sponsored by Cambridge University Hospitals NHS Foundation Trust. The aim of the study is to test the hypotheses that:

- a) Immune modulatory therapy is superior to standard of care alone (in that reduction of exaggerated host immune response to COVID-19 in patients at late stage 1/early stage 2 disease, reduces the composite of progression of these patients to organ failure or death);
- b) Combination therapy with SGLT-2 and Endothelin Antagonism is superior to standard of care alone (in that antagonism of these pathways in patients at late stage 1/early stage 2 disease, reduces the composite of progression of these patients to organ failure or death);

More specifically, this study is evaluating the efficacy of the interventions of EDP 1815, or the combination therapy of Ambrisentan and Dapagliflozin taken together, compared to standard of care treatment.

Your patient has been selected for the EDP 1815 arm.

EDP 1815, an unlicensed pharmaceutical preparation of a single strain of bacteria in Phase 2 development, is administered orally, in a capsule formulation, as 2 capsules twice daily for 7 – 14 days. No prohibited concomitant medications and no interactions are currently known.

For further information on the study, I have enclosed a copy of the Participant Information Sheet for your reference, however, if you have any queries or require further information please contact the study team (**Insert local contact details including contact number and website if available**).

In the event of an emergency please call:

Insert emergency telephone number which must match the telephone number on the PIS

Should you have any concerns about your patient participating in the study, please feel free to contact a member of the study team

Yours Sincerely,

PI name

Study Team Contact Information:

Local Contact Name

Hospital

Role

Telephone number

Encs: Participant Information Sheet, version *(insert version number)* dated *(insert date)*